

WHAT IS CLAIMED:

1    1.    A method for providing an oxygen sensitive container that indicates the presence of  
2    oxygen inside the container, the method comprising:

3                 placing an oxygen sensitive material inside a sealable container;

4                 evacuating air from the sealable container and sealing the sealable container to  
5                 isolate the oxygen sensitive material from oxygen; and

6                 irradiating the sealable container with an effective amount of radiation to activate  
7                 the oxygen sensitive material such that the oxygen sensitive material undergoes a visual  
8                 change in the presence of oxygen after the oxygen sensitive material has been irradiated,  
9                 the visual change providing an indication of the presence of oxygen inside the sealable  
10                container.

1    2.    The method of claim 1, wherein the step of evacuating the air from the sealable container  
2    is performed in a vacuum.

1    3.    The method of claim 1, wherein the step of evacuating the air from the sealable container  
2    is performed in a non-oxygen gaseous environment.

1    4.    The method of claim 1, wherein the step of irradiating the sealable container uses gamma  
2    radiation to activate the oxygen sensitive material and to sterilize the sealable container and any  
3    contents thereof.

1    5.     The method of claim 1, wherein the oxygen sensitive material is a plastic material  
2     comprising a portion of a medical device and the sealable container is a sterile medical container,  
3     and wherein the step of placing the oxygen sensitive material inside the sealable container is  
4     accomplished by placing the medical device inside the sterile medical container such that the  
5     medical device undergoes no visual change until the sterile medical container is opened as long  
6     as no significant amounts of oxygen are present in the sterile medical container prior to the  
7     sterile medical container being opened.

1    6.     The method of claim 1, wherein the visual change of the oxygen sensitive material  
2     indicates a failure of the sealable container.

1    7.     The method of claim 1, wherein the visual change of the oxygen sensitive material occurs  
2     within 8 hours of exposure to a significant amount of oxygen.

1    8.     The method of claim 7, wherein the visual change of the oxygen sensitive material occurs  
2     within 1-2 hours of exposure to the significant amount of oxygen.

1    9.     Apparatus for indicating the presence of oxygen comprising:  
2                a sealable container that isolates contents of the container from ambient  
3                atmosphere when sealed; and  
4                an oxygen sensitive material located within the sealable container, the oxygen  
5                sensitive material being a material that undergoes a visual change when in contact with

6           oxygen once the oxygen sensitive material has been irradiated after the sealable container  
7           has been sealed to activate the oxygen sensitive material.

1       10.   The apparatus of claim 9, wherein the oxygen sensitive material comprises at least a  
2       portion of a medical device located within the sealable container such that the medical device  
3       itself is an oxygen indicator.

1       11.   The apparatus of claim 9, wherein the oxygen sensitive material comprises a piece of  
2       material fixed inside the sealable container and separate from any other contents of the sealable  
3       container.

1       12.   The apparatus of claim 9, wherein the visual change of the oxygen sensitive material  
2       indicates a failure of the sealable container.

1       13.   The apparatus of claim 9, wherein the oxygen sensitive material is an oxygen sensitive  
2       polymeric composition.

1       14.   The apparatus of claim 13, wherein the oxygen sensitive polymeric composition is a  
2       polycarbonate composition activated by an effective amount of gamma radiation.

1       15.   The apparatus of claim 14, wherein the effective amount of gamma radiation is between  
2       about 25 Kilograys to 45 Kilograys.

1    16.    The apparatus of claim 9, wherein the sealable container comprises:

2                a gas impermeable foil pouch; and

3                a cardboard protective packaging for the foil pouch.

1    17.    The apparatus of claim 16, wherein the gas impermeable foil pouch is a multi-layer foil  
2 package comprising:

3                a silicone oxide treated PET layer;

4                a foil layer;

5                a biaxially oriented nylon layer; and

6                a polyethylene layer.

1    18.    The apparatus of claim 9, wherein the oxygen sensitive material is formed as a generally  
2 planar chip of material and is operably positioned adjacent a backing material such that a  
3 combination of the backing material and the planar chip of material increase effective visibility  
4 of the visual change in the oxygen sensitive material over visibility of visual change of the  
5 oxygen sensitive material alone.

1    19.    The apparatus of claim 9, wherein the oxygen sensitive material undergoes the visible  
2 change within less than 8 hours after exposure to a significant amount of oxygen.

1    20.    The apparatus of claim 19, wherein the oxygen sensitive material undergoes the visible  
2 change within 1-2 hours after exposure to a significant amount of oxygen.

1    21.    The apparatus of claim 9, wherein the contents of the container include contents selected  
2    from the set consisting of: a medical device, a drug, a food product, or any combination thereof.

1    22.    The apparatus of claim 9, wherein the oxygen sensitive material is arranged to form at  
2    least one symbol that assists in interpreting the visible change of the oxygen sensitive material.